Will the project involve testing an experimental drug, device (including medical software or assays) or biologic?

Has the project received funding (e.g., federal, industry) to be conducted as a human subjects research study?

Is the primary intent of the project to contribute to generalizable knowledge (e.g., testing a hypothesis) AND has the project been designed in such a way that the findings will be generalizable (e.g., randomization of subjects; comparison of case vs. control)?

Will the project occur regardless of whether individuals conducting it may benefit professionally from it?

Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program?

Will the results of the project be published, presented or disseminated outside of the institution conducting it?

The project doesn’t appear to fit the definition of QI or program evaluation. Contact the HS IRBs Office for guidance.

The project appears to constitute QI and/or Program Evaluation and does not fit the federal definition of research. Further IRB review is not required. Ensure that all those associated with the project are aware that it is ongoing.

The project appears to constitute QI and/or Program Evaluation and does not fit the federal definition of research. Further IRB review is not required. In future publications/presentations, it is recommended you refer to this as QI/program evaluation and not as research.

The project doesn’t appear to fit the definition of QI or program evaluation. Contact the HS IRBs Office for guidance.

IRB review is likely required to address FDA requirements. Access the HS IRBs website for guidance.

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